



Growers & processors of:

- rope-cultivated mussels
- hard/soft shell clams
- oysters

March 25, 2003
Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD
USA 20852

To Whom It May Concern:

Reference: Docket Number 02N-0278
Prior Notice – Bioterrorism Act

We would like to make the following comments in reference to the timing and procedure for giving “Prior Notice” for shipments entering the US from our company, Atlantic Aqua Farms Inc., Prince Edward Island, Canada.

First of all please be aware that Atlantic Aqua Farms Inc is a shellfish processing company (Cultured Mussels and Oysters) operating and exporting to the US market on a twice –weekly basis since 1989. AAFI is a C-TPAT “approved” member, a Canadian Food Inspection Agency (CFIA) registered company, a QMP (HACCP equivalent!) approved processing facility and a FDA Certified Interstate Shellfish Shipper under license number PE 2329SS.

Our US Customers currently order on Tuesday mornings for Tuesday exit orders from our plant and on Friday mornings for Friday exit orders from our plant. The reason for this “Just In Time” ordering /delivery schedule is we/they are dealing with a “PERISHABLE” product that is very date sensitive. Our customers need to have firm orders from their retail and food service customers before they can order.

Any US Seafood Distribution company dealing with fresh perishable seafood would agree that it is very unrealistic for them to place an order before noon on a Monday (for example) for delivery on Thursday. They are still waiting for delivery of their previous PERISHABLE order and they certainly would not have a firm order from their customers (retail and food service users) this early in the “from harvest to seafood counter” chain. Even if our customers could accommodate us with this helpful information what is it going to cost them in lost sales? They will end up shorting themselves on product or dumping product because they ordered too many! Remember it is a “perishable product” they/we are dealing with! This added cost of “early ordering” for our customers (US Seafood Distribution companies) is before they factor in what it is going to cost them as the US purchaser or Importer (or their qualified agent) to submit the prior notice to USFDA. Factor in the added cost of amending the original prior notice with a quantity change that was not known at the time the original prior notice was submitted, costs of clerical errors, missed shipments and the list goes on all adding to their cost.

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Atlantic Aqua Farms recommends that LIVE PERISHABLE SEAFOOD product be given the following options:

- a) Be preceded by a prior notice to FDA by no less than four hours before the shipment arrives at the border for inspection. A four-hour pre-notification option would mean that an amendment would not be required and would lessen the administrative burden to all "partners" involved.
- b) That Canadian seafood shippers be able to have the option to provide the pre-notification information directly to FDA as an added option to the US based possibilities proposed in the regulations. This would mean, for our company alone, possibly 5 prior notices (by truck) on Tuesday and 10 prior notices (by truck) on Friday instead of a minimum of 120 of US based purchasers or their agents. This would lessen the administrative burden and cost to all partners (our US customers, USFDA, our common carrier and ourselves) involved.
- c) That we as a CTPAT approved seafood company in Canada be given the option of being able to indicate on both the registration and pre-notification electronic forms that we are "CTPAT" and/or are a CFIA registered plant. It should be an objective of USFDA to negotiate the same kind of expedited border inspection under the FDA bio-terrorism inspection as is being offered by US Customs under the CTPAT program.

We are very concerned that it is a very short window between final regulations being posted on October 12, 2003 and an effective date of December 12, 2003. We ask that you consider widening that window to a later effective date to give small companies like ourselves and our US Customers more time to prepare once the final regulations are posted.

AAFI has been very supportive of the CTPAT program and what it has done to assist our governments in preventing terrorism. We have developed and implemented a security program, at considerable cost, at our facility AND with our shipping partners in the trucking industry, our customs broker and US Customs. We support the objectives stated by FDA in the proposed Bio-terrorism Act however we feel strongly that it should not be more restrictive than necessary to meet its objective. It is important to Atlantic Aqua Farms Inc. that we do our part in protecting the channels of trade from terrorist infiltration. We feel strongly that as partners with our US customers and US Regulatory Agencies that there is a balance of "Secure" trade and "Realistic" trade. We all need to be conscious of the fact that we could be playing into terrorists hands if our "day to day" business is beyond realistic trade facilitation.

Thank you for considering our comments.

Yours truly,

A handwritten signature in black ink, appearing to be 'B. Fortune', with a long horizontal stroke extending to the right.

Brian Fortune
General Manager